



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/541,124

03/31/2006

Dominique M. Freeman

PEL-2784

4918

77845

7590

06/09/2010

Goodwin Procter LLP

Attn: Patent Administrator

135 Commonwealth Drive

Menlo Park, CA 94025-1105

EXAMINER

EDWARDS, LYDIA E

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

06/09/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/541,124	FREEMAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	LYDIA EDWARDS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-25,27-29 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28,29 and 34-40 is/are allowed.
- 6) ☒ Claim(s) 1-4,24,25,27,32 and 33 is/are rejected.
- 7) ☒ Claim(s) 5-23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/25/2010 and 3/3/2010</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Terminal Disclaimer***

The terminal disclaimer filed on 3/9/2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 3/27/2026 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Double Patenting***

The double patenting rejections of claims 1-28 have been withdrawn as a result of the above terminal disclaimer being filed and accepted.

### ***Response to Arguments***

Applicant's arguments filed 3/9/2010 have been fully considered but they are not persuasive.

Regarding applicant's argument that *claims 5-8 are not use claims, as they further limit the device of claim 1 by claiming specific composition of "the analyte detecting member", the arguments* have been fully considered and are persuasive. The 112 second paragraph rejections of claims 5-8 have been withdrawn.

In response to applicant's argument that "*There is no teaching Simons of detecting members using an optical method*", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Moreover, Simons discloses wherein an absorbent material [218] or an adjoining surface can serve as a test area [220] for the analyte detecting member [210] for measurements of blood characteristics, such as glucose measurements. As in existing glucose measurements techniques, a chemical reaction occurs when blood contacts the test area (Col 8, 19-25). The examiner deems Simons fully capable of

Art Unit: 1797

creating a chemical reaction that produces a type of luminescence such as bioluminescence, chemoluminescence, fluorescence, etc.

Applicant's arguments with respect to claim 3 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Objections***

Claim 27 is objected to for depending on a canceled claim, claim 26. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 recites the limitation "said fluid path". There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 24-25, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simons et al. (U.S. 6036924) in view of Lum et al. (GB 2335990) further in view of Betts et al. (US 5405510).

Regarding Claims 1, 4, 24 and 32-33, Simons et al. ('924) discloses a cartridge (246) having a plurality of analyte detecting members (210) mounted on said cartridge, the cartridge comprising cavities (wells, 44), a plurality of penetrating members (216 connected to 224) which are contained at least partially in the cavities and are slidably movable to extend outward from the openings on the cartridge (col. 5 lines 16-26). Simons et al. also discloses a plurality of chambers each associated with a cavity that are positioned along an outer periphery of the cartridge. An analyte detecting member is associated with each chamber and forms a portion of one wall of the plurality of chambers (Fig. 3A, 220 and col. 8 lines 19-29). Simons et al.

Art Unit: 1797

discloses that the test area can be the absorbent material 218 or the surface beneath it which is a wall of the chamber. Simons et al. discloses the invention as stated above regarding claim 1 and further discloses that the chamber is positioned substantially adjacent an outer periphery of the cartridge (Fig. 6D) and at least one opening in one of the chambers which leads fluid along a fluid path toward an analyte detecting member (col. 8 lines 19-22 and lines 29-35 and col. 7 lines 40-49).

Simons fails to disclose a position sensor coupled to the plurality of penetrating members, the position sensor utilizing position information of a penetrating member to determine a depth of penetration through a skin surface.

Lum et al. ('990) discloses that it is old and well known in the art to use a position sensor coupled to a penetrating member, the position sensor utilizing the position information of the penetrating member to determine the depth of penetration through the skin. In particular, Lum et al. discloses a penetrating member that uses a sensor that senses the different impedance values of the different layers of skin to determine information on which layer of skin the penetrating member is positioned within (p. 3, lines 4-7). Lum et al. further discloses that this information helps to minimize the trauma and pain of over-penetration as well as avoid the frustration and pain of unsuccessful blood sampling because of inadequate penetration (p. 3, lines 16-23). Lum et al. discloses that these advantages are especially pertinent to patients such as diabetics, who have to sample blood often (p. 1, lines 22-23). Simons et al. disclose that the cartridge of their body fluid sampling device may be used in conjunction with a glucometer (see abstract).

Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Simons et al. to include a position sensor coupled to the plurality of penetrating members, the position sensor utilizing position information of a penetrating member to determine a depth of penetration through a skin surface as made obvious by Lum et al. in order to avoid the problems associated with over-penetration or inadequate penetration.

Simons fails to disclose a memory on said device.

Betts et al. ('510) discloses memory on a analyte measuring system for fluid samples (Col 5, lines 16-65 and Col 6, line 34-59)

Art Unit: 1797

It would have been obvious to one of ordinary skill in the art to modify the device of Simons et al. and Lum et al. with a memory on the device as taught by Betts et al. to employ a means for calibration and analysis of the samples.

Regarding Claim 2, Simons ('924), discloses wherein the cartridge does not include any penetrating members (Figures 6b and 6d).

Regarding Claim 3, Simons ('924), discloses wherein said cartridge has a radial disc shape (Figure 6c and 6d).

Regarding Claim 25, Simons ('924), discloses multiple cartridges comprising penetrating members in cavities on said cartridge (Figures 1b, 4b and 5a).

*Allowable Subject Matter*

Claims 28-29 and 34-40 are allowed.

Regarding Claim 28, prior art fails to disclose a method for determining a concentration of an analyte in body fluid, comprising: collecting a sample of body fluid of about 500 nL or less; covering an electrochemical sensor with at least a portion of the sample; determining the concentration of the analyte in the sample using an optical technique.

Regarding Claim 29, prior art fails to disclose a method comprising: providing a cartridge having a plurality of wells; depositing an emulsion in the wells; scraping away emulsion from tops of the wells, in order to level the amount of emulsion in each well.

Regarding Claims 34-40, prior art fails to disclose the device of claim 33 further comprising an optical system.

Claims 5-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.



***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYDIA EDWARDS whose telephone number is (571)270-3242. The examiner can normally be reached on Mon-Thur 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571.272.1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYDIA EDWARDS/  
Examiner  
Art Unit 1797

LE

/Walter D. Griffin/  
Supervisory Patent Examiner, Art Unit 1797